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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,004	01/02/2002	Brendon Conlan	56104576-25	6499

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EXAMINER	
PHASGE, ARUN S	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/037,004	CONLAN ET AL.
	Examiner	Art Unit
	Arun S. Phasge	1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/2/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, 16-32, 34-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Egen et al. (Egen), U.S. Patent 5,336,387.

Egen discloses the claimed method and apparatus for the selective removal of at least one biological contaminant, including the claimed contaminants, from a biological compound, including the claimed compounds (see column 3, lines 52-55) comprising directing a first fluid stream having a selected pH to flow along a first selective membrane, directing a second fluid along the first membrane isolated from the first fluid stream thereby, applying at least one voltage potential across each of the fluid streams until the desired purity is obtained to recover the purified compound (see figure 1 and column 5, lines 10-55). The reference further discloses the third and fourth fluid streams (see figures 6a-6e and columns 14-17 for the discussion of the figures with separation and fractionation of compounds).

Therefore, since the Egen patent discloses each and every limitation, the claims are anticipated.

Claims 1-14, 16-32, 34-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Laustsen, U.S. Patent 5,437,774.

Laustsen discloses the claimed method and apparatus for the selective removal of at least one biological contaminant, including the claimed contaminants, from a biological compound, including the claimed compounds (see column 6, lines 35-52) comprising directing a first fluid stream having a selected pH to flow along a first selective membrane, directing a second fluid along the first membrane isolated from the first fluid stream thereby, applying at least one voltage potential across each of the fluid streams until the desired purity is obtained to recover the purified compound (see figures 1-9 and column 5, lines 10-55). The reference further discloses the third and fourth fluid streams (see figures 1-5 and columns 8-9). The reference further discloses the claimed range of the membrane's molecular weight cutoff (see column 7, lines 15-30).

Therefore, since the Laustsen discloses each and every limitation, the claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laustsen as applied to claims above, and further in view of Margolis, U.S. Patent 5,650,055.

The Laustsen patent while discloses that the direction of the electric field can be adjusted based upon a variety of reasons, fails to disclose the reversal of polarity (see col. 6, lines 5-23). The Margolis patent is cited to show the use of

the reversal of polarity in the electrophoretic separation of macromolecules, such as proteins to allow the desired proportion of the at least one species of macromolecules (see abstract).

Consequently, the invention as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the disclosure of the Laustsen patent with the teachings contained in the Margolis patent, because the Margolis patent teaches that the periodic reversal of polarity allows the desired purity of the compounds.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-114 of copending Application No. 09/887,208. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims of the prior application when read in light of the specification clearly encompass and render obvious the claims of the instant application.

The prior application does not disclose that the separation occurs concurrently. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the claims of the copending application, because the application of electric current would cause the movement of both the contaminant and the selected compound to occur.

Claims 1-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 09/887,371. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims of the prior application when read in light of the specification clearly encompass and render obvious the claims of the instant application.

The copending claims do not disclose that the isolation occurs concurrently across the membrane to separate the biological contaminant into another stream. It would have been obvious to one having ordinary skill in the art at the time the invention was made, because the application of the potential would cause the isolation across the membranes concurrently and would also separate the biological contaminant into another stream.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,464,851. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims of the prior patent when read in light of the specification clearly encompass and render obvious the claims of the instant application.

The reference does not disclose that the isolation occurs concurrently across the membrane to separate the biological contaminant into another stream. It would have been obvious to one having ordinary skill in the art at the time the invention was made, because the application of the potential would cause the

isolation across the membranes concurrently and would also separate the biological contaminant into another stream.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun S. Phasge whose telephone number is (571) 272-1345. The examiner can normally be reached on MONDAY-THURSDAY, 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Arun S. Phasge
Primary Examiner
Art Unit 1753

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